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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,594	11/07/2001	Eric Olson	UTSD:729US/SLH	8497
7590 07/12/2004				
Steven L. Highlander Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			EXAMINER BERTOGLIO, VALARIE E	
			ART UNIT 1632	PAPER NUMBER
DATE MAILED: 07/12/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/045,594	<b>Applicant(s)</b> OLSON ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Applicant's amendment filed 05/06/2004 has been entered. Claims 1-9, 13-18 and 20-105 have been cancelled. Claims 10-12 and 19 have been amended. Claims 10-12 and 19 are pending and currently under consideration.

#### ***Sequence Compliance***

The specification is now sequence compliant.

#### ***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The rejection of claim 19 under 35 U.S.C. 112, first paragraph is withdrawn in light of Applicant's arguments.

#### ***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

In light of Applicant's amendments to the claims, the rejection of claims 10-12 and 19 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The declaration filed on 05/06/2004 under 37 CFR 1.131 is sufficient to overcome the Ievolella and Ahmad references. Therefore the rejection of claim 10 under 35 USC 102 (a) as being anticipated by Ievolella and by Ahmad are withdrawn.

The rejection of claim 10 under 35 USC 102 (e) as being anticipated by Tang (EFD 01/21/2000; USSN 10/098841;US200201976791A1, SEQ ID NO:286) is maintained. Applicant argues that a review of the 01/21/00 priority document, USSN 09/488,725; SEQ ID NO: 8629, reveals that SEQ ID NO:8629 is a partial sequence and the priority date for Tang is thus 04/25/2000, which is after the date of 04/12/2000, on which Applicant's have declared to have been in possession of the nucleotide sequence encoding SEQ ID NO:2 of the instant application (refer to the declaration filed 05/06/2004).

In response, SEQ ID NO:8629 of '725 is a partial nucleic acid sequence of SEQ ID NO:1 of the instant application. The claims, however, are drawn to a nucleic acid molecule encoding SEQ ID NO:2. Nucleotides 132-923 of SEQ ID NO:1 of the instant application represent the coding sequence for the polypeptide set forth in SEQ ID NO:2. This nucleic acid has been aligned to and is a 100% match to nucleotides 301-1092 of SEQ ID NO:8629 of USSN 09/488,725 (priority document for Tang with an EFD of 01/21/2000; alignment enclosed). Therefore, the proper effective filing date for Tang is 01/21/2000, which is prior to the date set forth in Applicant's declaration stating that Applicant was in possession of the claimed nucleic acid on 04/12/2000. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

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Claims 11,12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang as applied to claim 10 above, and further in view of Capon et al., U.S. Patent Number 5,116,964.

Claims 11,12 and 19 are directed to an isolated and purified nucleic acid encoding SEQ ID NO:2 and further comprising a promoter active in eukaryotic cells (claim 11), further comprising a recombinant vector (claim 12), or encoding a fusion polypeptide comprising SEQ ID NO:2.

The teachings of Tang are discussed above. Tang did not teach use of a promoter or a recombinant vector, or a nucleic acid molecule encoding a fusion polypeptide comprising SEQ ID NO:2.

Capon taught use of a recombinant vector comprising elements such as a replication site and marker sequences (col. 26, lines 57-68) and a promoter (col. 27, line 2-col. 28, line 28). Capon taught that the use of a recombinant vector comprising expression control and replicative sequences aids in achieving a high level of expression (col. 27, lines 10-15). Capon also taught fusion proteins comprising immunoglobulin polypeptides fused to "ligand binding partners", which are defined as including hormones and growth factors (see column 2, lines 14-19). At column 4, lines 38-43, Capon stated that the immunoglobulin (Ig) fusions of the invention "serve to prolong the in vivo plasma half-life of the ligand binding partner..." and "facilitate its purification by protein A". Also taught are recombinant materials for making such a fusion protein, vectors and expression; see columns 15-16. Capon states that the DNA sequences for the immunoglobulin chains were well known in the art at the time the invention was made, see column 15 beginning at line 40.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the nucleic acid of Tang to make immunoglobulin fusions as taught by Capon and to use recombinant vectors and promoters to achieve a high level of hybrid immunoglobulin expression. The person of ordinary skill in the art would have been motivated to make the modification in view of Capon's disclosure that immunoglobulin fusion proteins facilitate purification of desired proteins and recombinant vector sequences and promoter elements allow for high level expression. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the cited prior art.

***Conclusion***

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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PRIMARY EXAMINER  
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Art Unit 1632